

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

ATE: January 25, 1979

SUBJECT: Natural Herbal Flea Collar
EPA File Symbol: 42443-R

FROM: Byron T. Backus
IRB-TSS

TO: Franklin Gee (PM-17)
IRB/TSS
Applicant: Natural Research People, Inc.
South Rte., Box 12
Lavinia, MT 59046

Active Ingredients:

Oil of Pennyroyal (Eurafrican).....	2.000%
Eucalyptus.....	1.000%
Cedar Oil.....	0.500%
Citronella.....	0.500%
Rue.....	0.125%
Inert Ingredients:.....	95.875%

Recommendations:

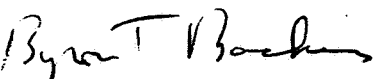
1. The applicant has supplied sufficient information so that long-term studies (such as oncogenicity) are not required for either this product or its active ingredients. As indicated by the applicant, European Pennyroyal, Eucalyptus ("Eucalyptus globulus leaves"), Rue ("Tansy") and Citronella are on the GRAS list. The first 3 are in 21 CFR 121.1163, and Citronella is in 21 CFR 121.1164. Cedarwood Oil, while not on the GRAS list, is used to a considerable extent in soaps and perfumes.
2. All of these "Active Ingredients" are being obtained in normal channels of trade from manufacturing suppliers. They are not being produced by the applicant.
3. From the standpoint of human and pet safety, IRB-TSS will require the following studies on the formulation without the cotton (i.e., on the [REDACTED] active ingredient mixture which is used to coat the cord):
 - i). Acute Oral DL50.
 - ii). Acute Dermal LD50, with skin irritation scores at 24 and 72 hours (this would satisfy the Dermal

Irritation Study requirement). If data based on testing with at least 5 animals per sex with abraded skin are submitted showing the dermal LD50 is greater than 2 g/kg for the 24-hour period, along with no or fairly minor skin irritation, no further testing at other dose levels would be necessary.

It is unlikely that the complete collar (including the cotton cord) could or would be ingested. If a child or pet was to chew on this product, the material swallowed would be the waxy coating. Similarly, dermal contact would primarily be to the waxy coating, rather than the cotton cord.

The Agency has not been generally requiring eye irritation studies for dog collar products.

4. Since efficacy testing will be conducted on dogs, observations should also be made on areas of contact with the herbal flea collar. A complete report of local skin effects should be reported. If efficacy studies are conducted on cats, similar observations should be made on this species.
5. If these data indicate adverse toxicological effects, additional studies may be required.
6. The Regulations, FR40, #129, July 3, 1975, p. 28278 state: Examples of statements or representations in the labeling which constitute misbranding include:...Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous,"...or "nontoxic to humans and pets"...and...Contains all natural ingredients." The statements which appear on the proposed product label are very similar to the examples given as constituting misbranding, particularly as they can be construed as comparative claims to other products.
7. The applicant is proposing the toxicity category II signal word (WARNING): if this product has relatively minor or no adverse toxicological effects, then the appropriate signal word should be "CAUTION." There is also no child hazard statement on the proposed label.


Byron T. Backus
IRB/TSS

